EXHIBIT 156

Case: 1:17-md-02804-DAP Doc #: 1960-50 Filed: 07/23/19 2 of 29. PageID #: 139256

From: Brantley, Eric

Sent: Tuesday, April 21, 2015 3:08 PM

To: Jones, Heather

Subject: Emailing: DEA-53013rev00, DEA-53014rev00, DEA-53015.01formRev01,

DEA-53015.02formRev01, DEA-53015.03formRev00, DEA-53015.04formRev00,

DEA-53015.05formRev00, DEA-53015rev00, DEA-53012rev00

Attachments: DEA-53013rev00.doc; DEA-53014rev00.doc; DEA-53015.01formRev01.docx;

DEA-53015.02formRev01.docx; DEA-53015.03formRev00.docx;

DEA-53015.04formRev00.docx; DEA-53015.05formRev00.docx; DEA-53015rev00.doc;

DEA-53012rev00.doc

Heather,

Attached are the SOPs for Suspicious Order Monitoring

Thanks,

Eric

Your message is ready to be sent with the following file or link attachments:

DEA-53013rev00

DEA-53014rev00

DEA-53015.01formRev01

DEA-53015.02formRev01

DEA-53015.03formRev00

DEA-53015.04formRev00

DEA-53015.05formRev00

DEA-53015rev00

DEA-53012rev00

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

STANDARD OPERATING PROCEDURE

an endo health solution

Title: CUSTOMER DUE DILIGENCE VISITS

No.: **DEA-53013** Version: **00** Effective: **12/23/2013**

Department: **DEA COMPLIANCE**

PURPOSE: The purpose of this SOP is to provide guidance for Qualitest employees and/or

third party contractors investigating Qualitest primary and secondary customers

for the potential risk of diversion of Controlled Substances and/or List 1

Chemicals.

SCOPE: This SOP applies to all Qualitest customers and secondary customers identified

through chargeback data and/or other intelligence.

DEFINITIONS:

Investigator A person authorized by the Qualitest Director, DEA Compliance or

Manager, Customer Due Diligence & SOM to conduct customer due diligence site visits. This includes Qualitest employees and

third party contractors.

Suspicious Order An order for a Controlled Substance or List 1 chemical which is of

an unusual size, frequency, and/ or deviates substantially from a

normal pattern.

Boundary

Controlled Substance A drug or other substance, or immediate precursor, included in

schedule I, II, III, IV, or V in Title 21 U.S.C.

List 1 Chemical A chemical specified by regulation of the Attorney General as a

chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of

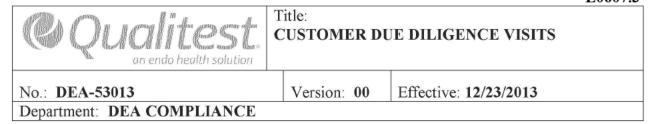
the controlled substance.

RESPONSIBILITY: The SOM team has the primary responsibility for compliance with this

SOP.

SAFETY: N/A

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REFERENCES: Identifying, Blocking and Reporting Suspicious Orders SOP

ATTACHMENTS: N/A

PROCEDURE:

Typical reasons for site visits

- A. Customer due diligence site visits shall be considered under the following circumstances:
 - SOM team requests a visit when more information is needed in approving a new customer account request for Controlled Substances or List 1 Chemicals.
 - 2. SOM team requests a visit based on analysis and/or investigation findings.
 - 3. SOM Advisory Board requests a visit during monthly review of customers.
 - 4. SOM team requests a visit when a customer requests to begin ordering Controlled Substances, List 1 Chemicals or is seeking a boundary increase.

II. Conducting Site Visits

- A. Investigators must schedule and complete the site visit within a reasonable amount of time from the request
- B. The completed site visit report must be submitted within a reasonable period of time after the visit is concluded. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will determine a reasonable period of time based on factors such as the number of customers visited, and locations.
- C. Investigations are scheduled with the owner or Pharmacist in Charge (PIC), and are conducted at the customer's DEA registered location.
- D. All visits must be documented on the appropriate checklist based on the customer class of trade. All requested documentation will be collected; including dispensing records void of patient identifying information.
- E. Reports must be submitted to the Director, DEA Compliance and Manager, Customer Due Diligence & SOM for review. The reports must be uploaded to the repository as part of the customer's file pursuant to the Record Retention Policy.

III. Investigation

A. The Investigator will be given all pertinent information about the customer prior to the visit.

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Department: DEA COMPLIANCE		

- B. The investigator must document obvious signs of potential diversion including but not limited to:
 - 1. Illicit drug use or transactions outside and around pharmacy
 - 2. Long lines of people waiting at the pharmacy
 - 3. Lack of a front end inventory
 - 4. Significant number of out-of-state vehicles parked at pharmacy
 - 5. FedEx or UPS shipping materials that could be evidence of internet activity



- IV. Investigation Review
 - A. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will review the findings. The Investigator may be consulted during this process.
 - B. If it is determined that there is significant risk of potential diversion, action may be taken against the customer after review by the Advisory Board. This may include denial of the new customer's application for purchasing Controlled Substances or discontinuing the sale of Controlled Substances with an existing customer or blocking the customer from ordering Controlled Substances and List 1 Chemicals. Any customer that is dropped due to significant risk of diversion will be reported to DEA.

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- C. Prompt notification is sent to the sales team, customer service and the customer by the Director DEA Compliance or the Manager, Customer Due Diligence & SOM.
- D. Customers that have been blocked from ordering Controlled Substances and List 1 Chemicals may request to have their ability to order Controlled Substances and List 1 Chemicals reinstated. Consideration of reinstatement of the customer will be made after a reasonable period of time has passed and after the reasons for the block have been mitigated as established by the SOM Team. The SOM Advisory Board will review all pertinent information for account reinstatement during the next scheduled SOM Advisory Board meeting. A significant investigation and remediation detail must be provided before reinstating the customer's Controlled Substance ordering ability.

END SOP

REVISION HISTORY: REV00 – New SOP

STANDARD OPERATING PROCEDURE



Title:

IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS

No.: **DEA-53014** Version: **00** Effective: **12/23/2013**

Department: **DEA COMPLIANCE**

PURPOSE: The purpose of this SOP is to provide guidance on identifying, blocking and

reporting Suspicious Orders. It also provides guidance on reviewing,

documenting, and resolving excessive or Suspicious Orders in order to comply with the requirements of the Controlled Substance Act and Part 21 of the CFR.

SCOPE: This procedure applies to all customers and all customer orders of Controlled

Substances and/or List 1 Chemicals (as defined below), and all Qualitest

personnel involved with the initiation, processing or review of customer orders for

Controlled Substances and List 1 Chemicals.

DEFINITIONS: Suspicious Order An order for a Controlled Substance or List 1

Chemical which is of an unusual size, frequency, and/or deviates substantially from a normal pattern.

Controlled Substance A drug or other substance, or immediate precursor,

included in schedule I, II, III, IV or V of Title 21 of

U.S.C.

List 1 Chemical A chemical specified by regulation of the Attorney

General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 of U.S.C. and is important to the manufacture of the

controlled substances.

Boundary

Order of Unusual Size A Controlled Substance order that is significantly

larger than the orders usually placed by the

customer or by customers of the same size and class

of trade.

Unusual Frequency A Controlled Substance order that is placed

significantly more frequent than orders normally placed by customer or customers the same size and

class of trade.

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Title:

IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS

No.: **DEA-53014** Version: **00** Effective: **12/23/2013**

Department: **DEA COMPLIANCE**

Unusual Pattern A Controlled Substance order that is a significant

deviation from customer's normal ordering pattern or the ordering pattern of customers of the same

size and class of trade.

SOM Tool An Information Technology program that uses an

algorithm to identify suspicious orders.

RESPONSIBILITY: The Qualitest SOM team is responsible for following this SOP

SAFETY: N/A

REFERENCES: Qualitest SOP Due Diligence Investigations

Qualitest SOP Cage/Vault SOM

ATTACHMENTS: N/A

PROCEDURE:

- Order Review
 - A. Every Controlled Substance held order must be reviewed by the SOM team to determine if it is a Suspicious Order as defined by 21CFR 1301.74(b) and this SOP. As necessary, the SOM team will contact customer service and/or the customer to obtain additional information regarding the order. Controlled Substance orders are deemed suspicious if they meet one or more of the below:
 - 1. Order is of unusual size
 - 2. Order is of unusual frequency
 - 3. Order deviates substantially from normal pattern
 - B. Controlled Substance orders deemed suspicious must be reported to DEA by the Director, DEA Compliance or when appropriate, the Manager, Customer Due Diligence & SOM.



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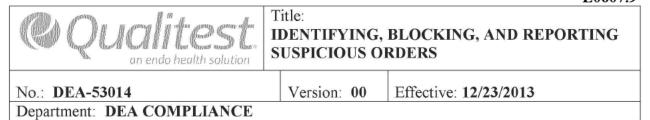
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	Title: IDENTIFYING, BLOCKING, AND REPORTING SUSPICIOUS ORDERS		
No.: DEA-53014	Version: 00	Effective: 12/23/2013	
Department: DEA COMPLIANCE			

- D. Controlled Substance orders of unusual size can either be the result of an order error or intentional orders placed by the customer. The SOM team must determine if the Controlled Substance order is an error or intentional order.
 - 1. Order entry errors are NOT reported to DEA as suspicious orders and must not be shipped. These orders do not count against the customer's boundary, and the accrual is readjusted.
 - 2. Intentional orders are evaluated using order history, experience and information provided by customer.
 - a. The Controlled Substance order is released if justified
 - b. The Controlled Substance order is blocked if not justified
 - c. The Controlled Substance order is blocked and reported to DEA if not justified and suspicious.
- E. Controlled Substance orders of unusual frequency are determined by the SOM tool or SOM team review.
 - 1. Frequency is determined using order history.
 - a. The Controlled Substance order is released if justified
 - b. The Controlled Substance order is blocked if not justified
 - c. The Controlled Substance order is blocked and reported to DEA if not justified and suspicious.
- F. Controlled Substance orders that deviate substantially from the normal ordering pattern are determined by the SOM tool or SOM team review. Substantial deviations may include but are not limited to:
 - 1. Orders for an unusually high percentage of a particular strength of a Controlled Substance.
 - 2. Orders for an unusually high percentage of Controlled Substances compared to non-controlled substances.
 - Other deviations based on the knowledge and experience of SOM team.
 - The Controlled Substance order is released if justified
 - The Controlled Substance order is blocked if not justified
 - The Controlled Substance order is blocked and reported to DEA if not justified and suspicious
- Π. Evaluation and Resolution of Held Controlled Substance Orders

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- A. When the SOM team releases the held Controlled Substance order, the SOM team must ensure that the reasons for releasing the order and all supporting information have been documented and saved pursuant to the Record Retention Policy.
- B. When the SOM team blocks a Controlled Substance order but does not deem the order Suspicious, the SOM team must ensure that the reasons and all supporting information have been documented and saved pursuant to the Record Retention Policy. The sales and/or customer service team will notify customer of all blocked Controlled Substance orders.
- C. When the SOM team blocks a Controlled Substance order and deems it Suspicious, the SOM team must ensure the reasons and all supporting information have been documented and saved pursuant to the Record Retention Policy prior to submitting the order to Director, DEA Compliance or designee for reporting to DEA.
- D. If the SOM team is unable to make a decision based on information available:
 - The Controlled Substance order is held as well as subsequent Controlled Substance orders until additional information is obtained and/or a site visit is completed pursuant to the Due Diligence Site Visit SOP.
- E. Based on the findings of the site visit:
 - The Controlled Substance order is released and consideration is given to evaluating the customer's boundary
 - 2. The Controlled Substance order is blocked and reported to DEA
 - 3. Customer may be terminated from purchasing Controlled Substances
 - 4. If a customer is reported to DEA as a suspicious customer, the customer will be terminated from purchasing Controlled Substances.

END SOP

REVISION HISTORY: REV00 – New SOP

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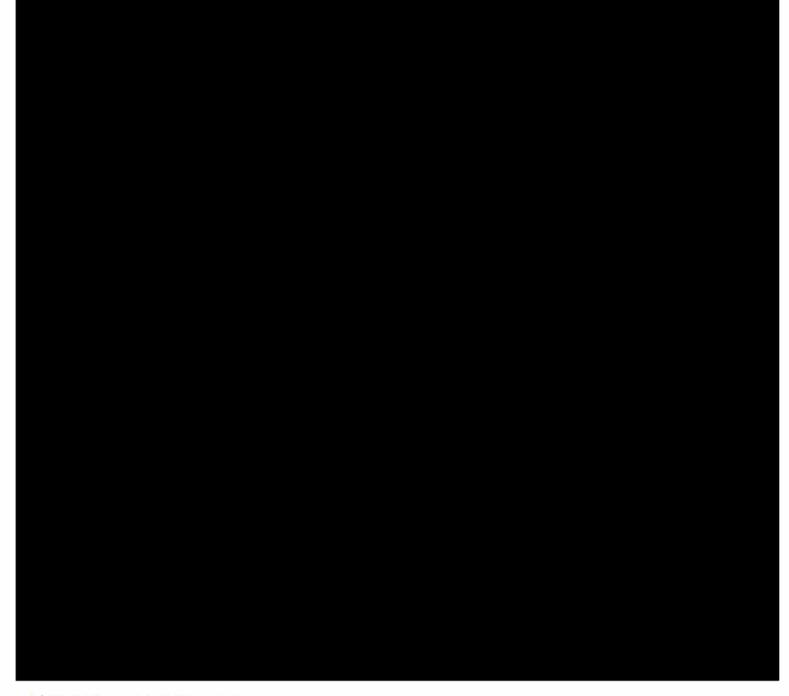


Title:

WHOLESALE DISTRIBUTOR/ CHAIN DISTRIBUTION CENTER QUESTIONNAIRE

Form No.: **DEA 53015.01** Version: **01** Effective: **07/15/2014**

Department: DEA



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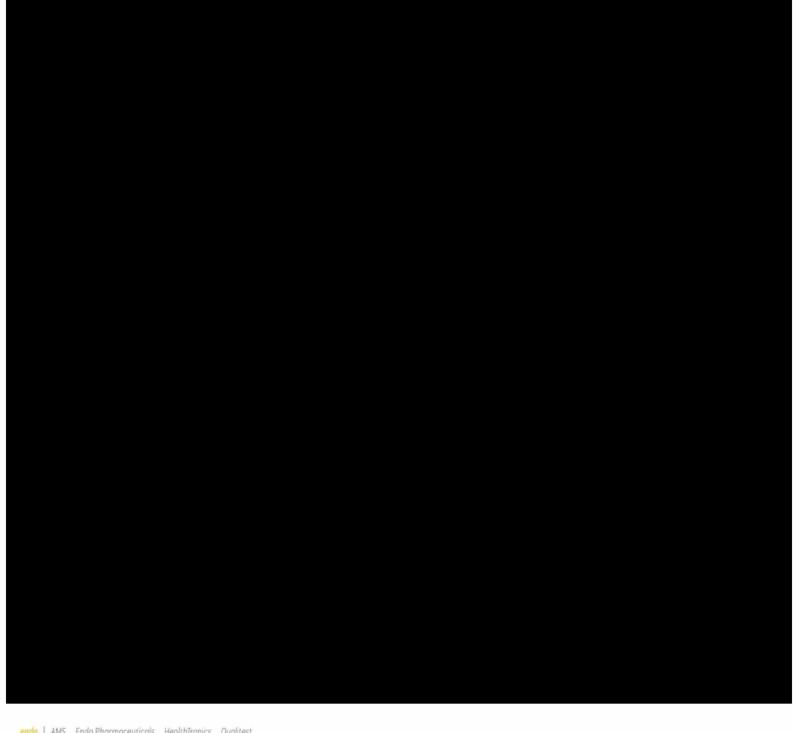
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Yes ☐ No ☐ # of accounts Click here to enter text. # receiving controlled substances Click Veterinary Wholesaler here to enter text.

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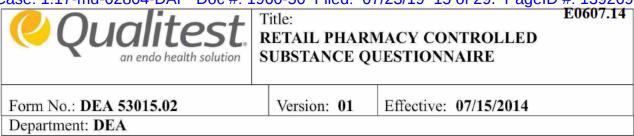
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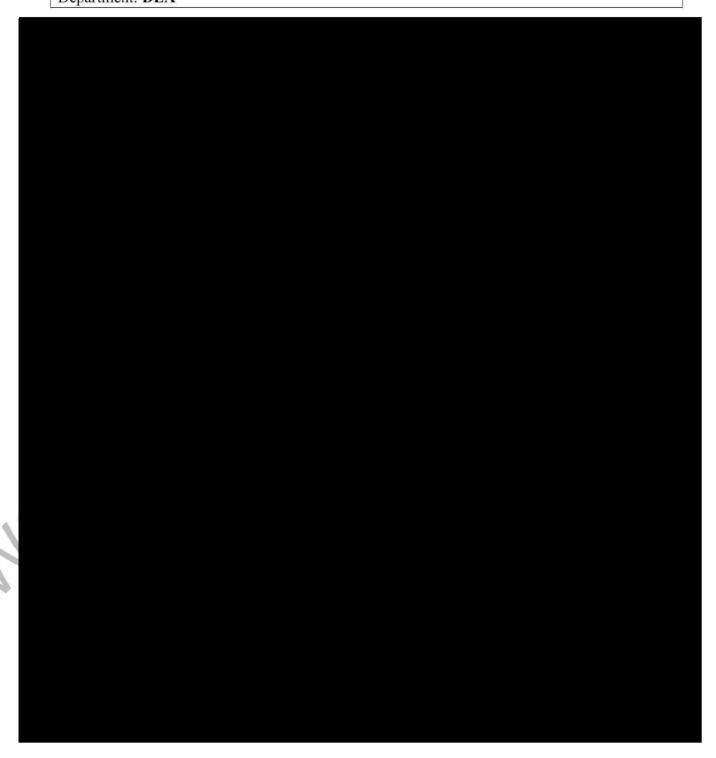


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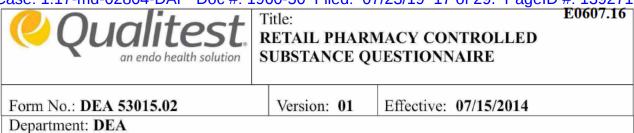
Title:
RETAIL PHARMACY CONTROLLED
SUBSTANCE QUESTIONNAIRE

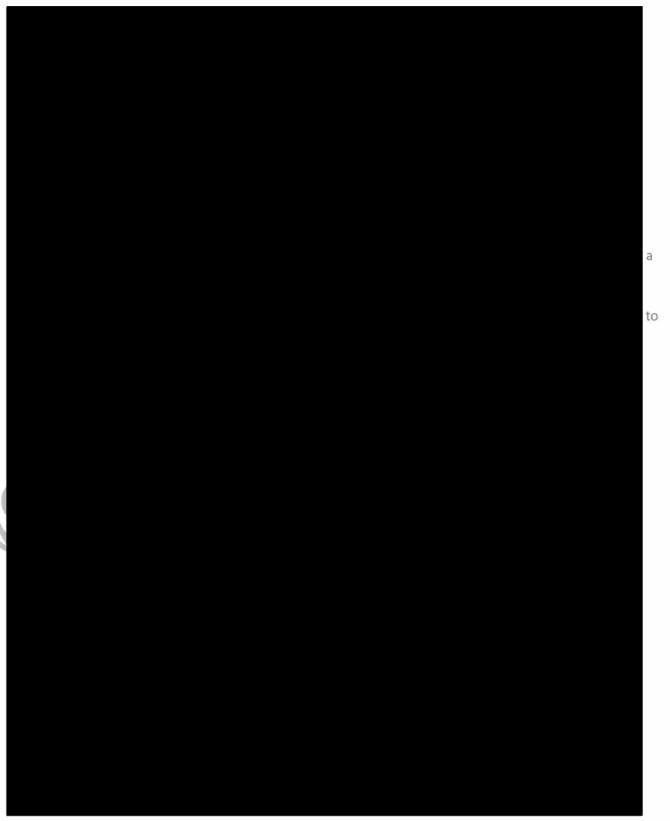
Form No.: DEA 53015.02 Version: 01 Effective: 07/15/2014
Department: DEA



Owner Information

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Title: RETAIL PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE an endo health solution Form No.: **DEA 53015.02** Version: 01 Effective: 07/15/2014 Department: **DEA**



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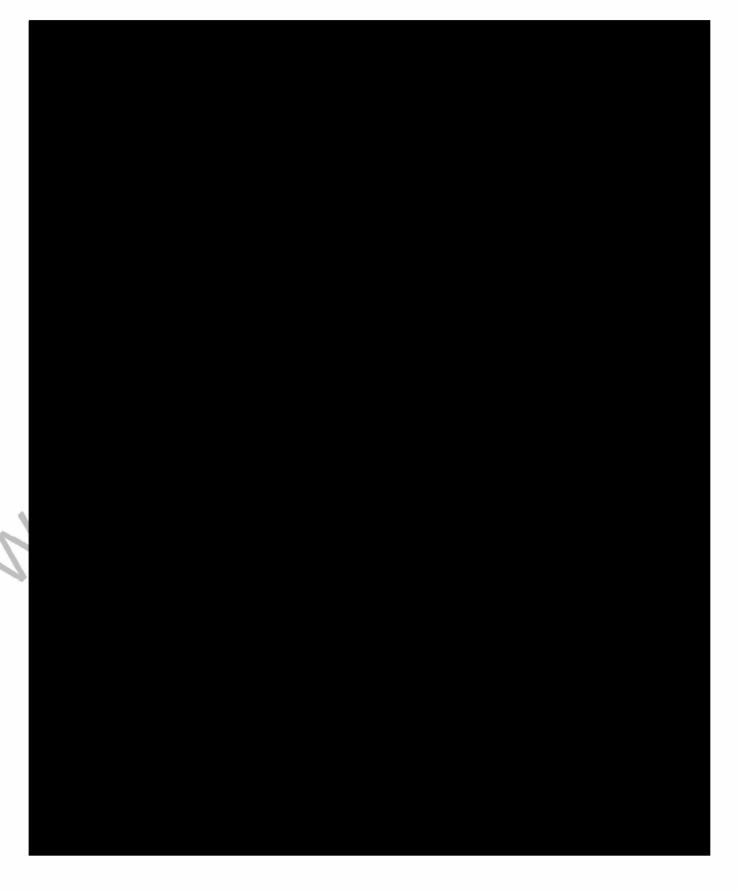
Case: 1:17-md-02804-DAP Doc #: 1960-50 Filed: 07/23/19 19 of 29. PageID #: 139273

Qualitest.
an endo health solution

Title: E00
MAIL ORDER PHARMACY CONTROLLED
SUBSTANCE QUESTIONNAIRE

Form No.: **DEA-53015.03** Version: **00** Effective: **07/15/2014**

Department: DEA

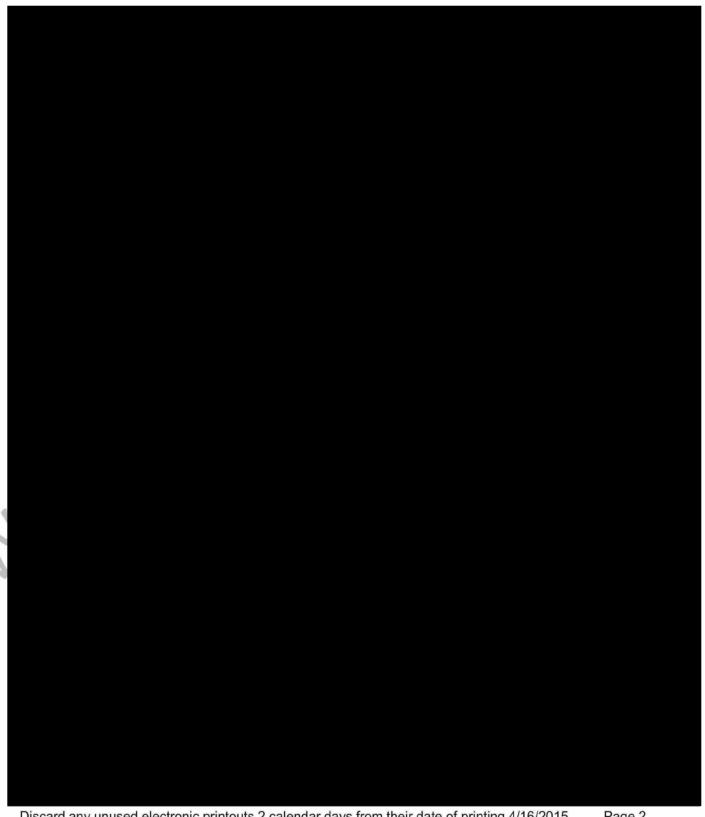




Title: MAIL ORDER PHARMACY CONTROLLED SUBSTANCE QUESTIONNAIRE

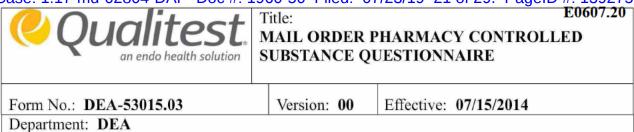
Form No.: **DEA-53015.03** Version: 00 Effective: 07/15/2014

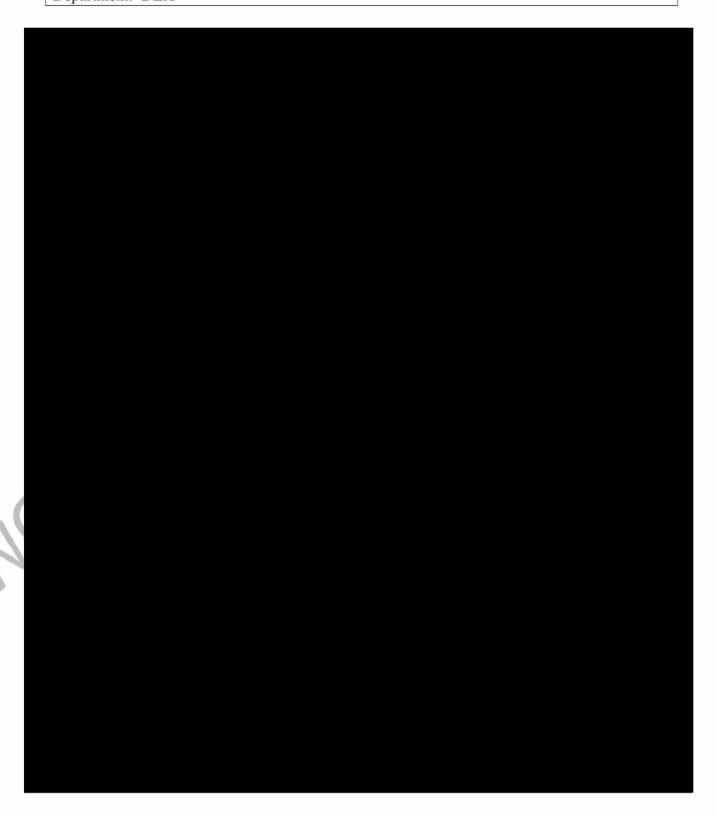
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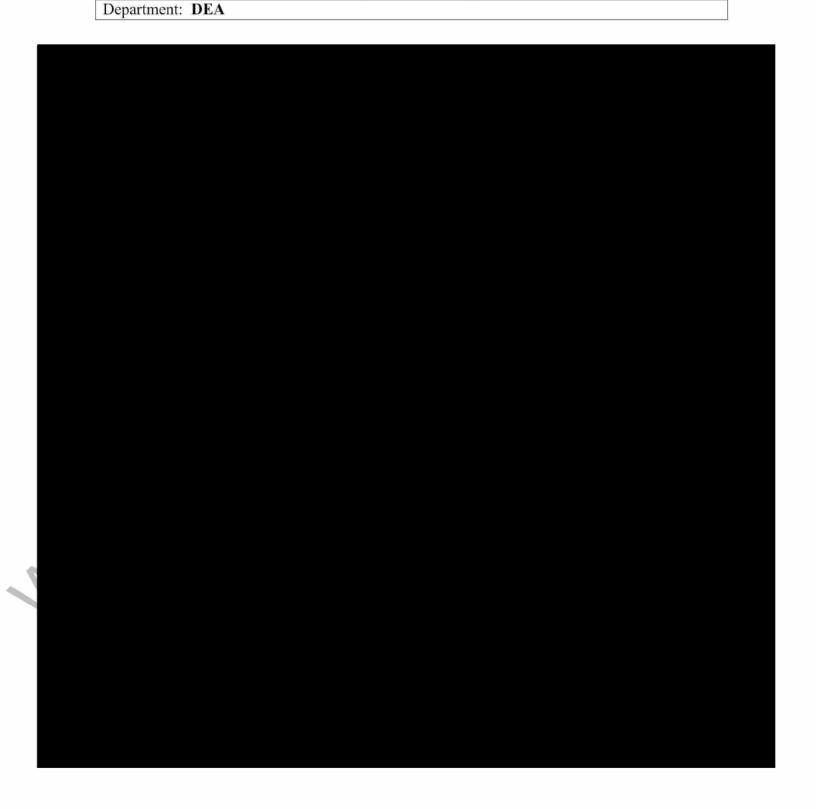
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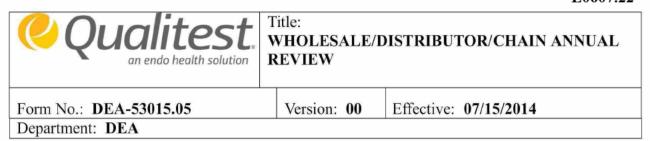
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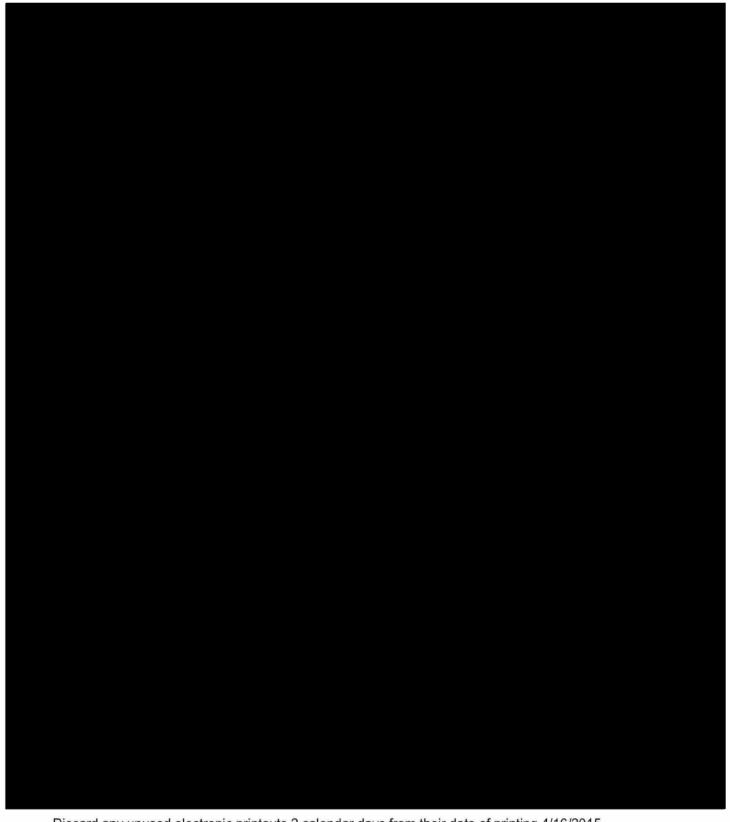
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Form No.: DEA-53015.04

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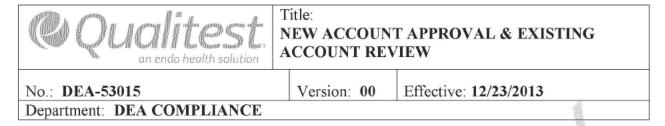


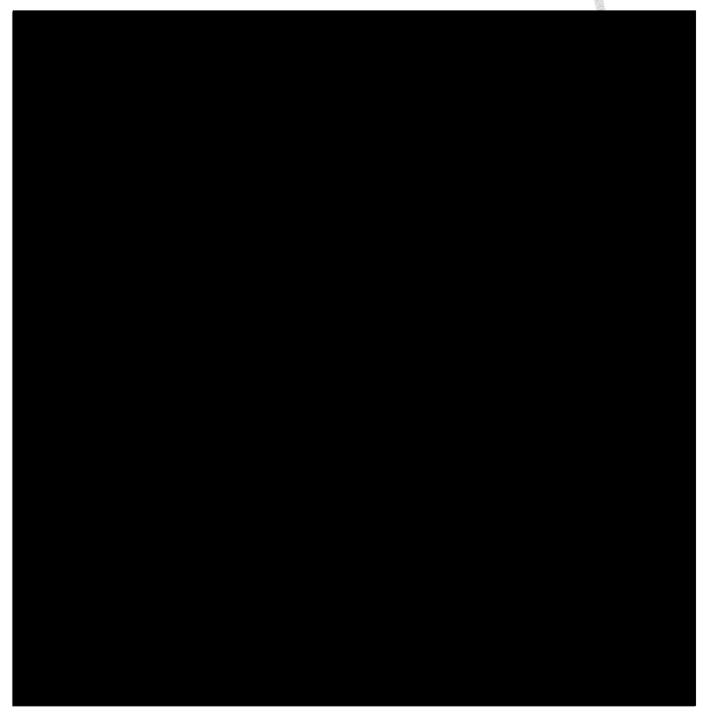




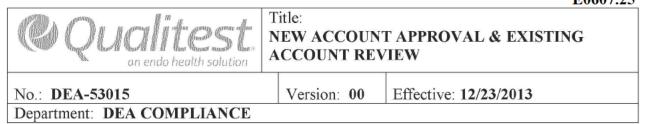


STANDARD OPERATING PROCEDURE





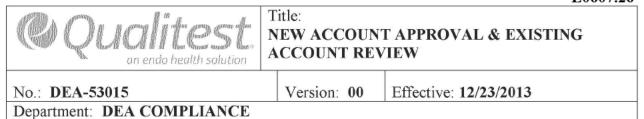
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- E. If red flags are identified during review, the SOM team may request additional information related to the red flag from the potential customer.
- F. The final decision to approve or reject the account with regard to the ability to order Controlled Substances or List 1 Chemicals is made on whether the customer poses an unreasonable risk for the diversion of Controlled Substances.
- G. All information related to the final decision must be documented and saved pursuant to the Record Retention Policy.

END SOP

REVISION HISTORY: REV00 – New SOP

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STANDARD OPERATING PROCEDURE

an endo health solution

Title:

CAGE / VAULT SUSPICIOUS ORDER MONITORING

No.: **DEA-53012** Version: **00** Effective: **12/23/2013**

Department: **DEA COMPLIANCE**

PURPOSE: To provide requirements for monitoring and reporting by cage/vault distribution

center employees and CIII-V order entry employees customer orders that are of

unusual size, frequency or deviates from normal pattern.

SCOPE: This procedure applies to Qualitest cage / vault distribution center employees as

well as employees responsible for CIII-V order entry and 222 form entry.

DEFINITIONS: Order of Interest An order that appears based on the skill, customer

knowledge and experience of the Qualitest employee to significantly deviate from the

customer's normal ordering pattern.

Controlled Substance A drug or other substance, or immediate precursor,

included in schedule I, II, III, IV, or V in Title 21

U.S.C.

List 1 Chemical A chemical specified by regulation of the Attorney

General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of the

controlled substance.

Suspicious Order An order for a controlled substance or List 1

chemical which is of an unusual size, frequency, and/or deviates substantially from a normal pattern.

RESPONSIBILITY: Cage / vault distribution center employees, CIII-V order entry and 222

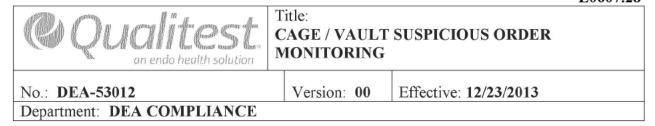
entry employees are responsible for the execution of this SOP.

SAFETY: N/A

REFERENCES: N/A

ATTACHMENTS: N/A

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PROCEDURE:

I. Controlled Substance or List 1 Chemical Orders of Interest



- B. If during the course of entering or picking orders for Controlled Substances or List 1 chemicals the employee identifies an order of interest, the employee notifies his /her supervisor. The supervisor alerts the SOM team for further review.
- C. The SOM team reviews the order and follows the Identifying, Blocking & Reporting SOP.
- D. If the order is deemed suspicious it is reported to the DEA by the Director, DEA Compliance or designee.

END SOP

REVISION HISTORY: REV00 – NEW SOP